Medical Innovation: Using mechatronics engineering to reduce inequities in healthcare

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Contents

Contents i

List of Figures vi

List of Tables xi

Nomenclature xv

Abstract xix

I Background and Context **1**

1 Introduction **3**

1.1 Preface 5

2 Medical innovation **9**

2.1 Drivers for innovation 9

2.1.1 Access to care 12

2.1.2 Non-specific and specific interoperability 14

2.2 Scales of innovation 16

2.3 Innovation uptake 18

2.3.1 Clinician-engineer relationship 19

2.3.2 Regulatory 21

2.4 Summary 22

II Diabetes Technologies **25**

3 Pressure for innovation **27**

3.1 Diabetes in New Zealand 29

3.1.1 Systemic 30

3.1.2 Personal: A story of inequities 34

3.1.2.1 The only positive thing about inequity is the feedback loop . . . 35
3.2 Summary . . . 38

4 One small driver for big change **41**
4.1 Treatment of DM . . . 43
4.1.1 T1D . . . 46
4.1.2 T2D . . . 49
4.1.3 Who has them currently - and who doesn't? . . . 51
4.1.4 Benefits . . . 54
4.1.4.1 Control, short-acting basal . . . 54
4.1.4.2 Health outcomes . . . 55
4.2 Financial aspects . . . 56
4.2.1 Direct savings . . . 57
4.2.2 Indirect savings . . . 58
4.2.3 Direct Costs . . . 60
4.2.4 Primary/education costs . . . 61
4.2.5 Total potential costs . . . 64
4.3 ULC-Pump . . . 66
4.3.1 Design philosophy . . . 66
4.3.1.1 Open . . . 66
4.3.1.2 The pirate's pump [hackability] . . . 70
4.3.2 Additional developments beyond typical . . . 72
4.3.3 Results . . . 75
4.3.4 Critical next steps . . . 76
4.3.4.1 The pirate's pump [patch] . . . 76
4.3.4.2 Actually ensuring uptake . . . 78
4.4 Summary . . . 81

5 Continuous glucose monitors **83**
5.1 Current blood glucose monitoring . . . 83

5.1.1 Glucose monitoring in type-one diabetes . . . 84
5.1.2 Glucose monitoring in type-two diabetes . . . 86
5.2 Current CGM use . . . 88
5.2.1 Benefits of CGM . . . 89
5.2.2 Limitations . . . 91
5.2.2.1 Locked out . . . 92
5.3 Biomedical optic blood continuous glucose monitor . . . 93
5.3.1 Benefits . . . 96
5.4 Economics . . . 98
5.5 Summary . . . 101

6 Coming full circle: Closing the loop **103**
6.1 Low-cost realisation . . . 104
6.1.1 Personalisable - digital twins . . . 104
6.1.1.1 ICING-2 model adoption . . . 105
6.1.1.2 Validation . . . 113
6.1.1.3 Current role . . . 116
6.2 Benefits . . . 117
6.2.1 Health . . . 118
6.2.1.1 Smart health . . . 120
6.2.2 Economic . . . 122
6.3 Summary . . . 122

III Dual Ventilation System **125**

7 Caring is sharing? **127**
7.1 Multiple ventilation . . . 128
7.1.1 Patient matching . . . 132
7.2 Series ventilation . . . 134
7.3 Summary . . . 136

8 Main elements **137**
8.1 Sensor . . . 139

8.1.1 Alternate configurations . . . 143
8.1.1.1 Operational Range . . . 145
8.1.1.2 Resolution . . . 146
8.2 PEEP valve . . . 147
8.3 Off-the-shelf components . . . 151
8.3.1 One-way valve . . . 151
8.3.2 Filters . . . 152
8.3.3 Airway tubing . . . 152
8.4 Summary . . . 153

9 ACTIV specifics — switch it up **155**
9.1 Valve . . . 156
9.2 Electrical System . . . 158
9.2.1 Controller . . . 159
9.2.2 GUI . . . 160
9.3 Control system . . . 161
9.3.1 Filtering . . . 162
9.3.2 Changing state . . . 164
9.4 Summary . . . 166

10 Combined ACTIV system **167**
10.1 Validation method . . . 167
10.1.1 Balancing Process . . . 169
10.1.2 Data gathering . . . 171
10.2 Results . . . 171
10.3 Discussion . . . 174
10.3.1 Safety Considerations . . . 178
10.3.2 Other Considerations . . . 180
10.4 Summary . . . 181

11 Conclusions and future work **183**
11.1 Conclusions . . . 183

11.2 Future work . . . 187
11.2.1 Diabetes technologies . . . 187
11.2.2 Dual ventilation . . . 188

IV End matter **191**

Bibliography . . . 193

A Diabetes technologies **267**
A.1 Pump pictures . . . 267
A.1.1 Complete economic analysis . . . 269
A.2 Closed-loop . . . 273
A.2.1 Approved ethics confirmation and information sheet . 279

B ACTIV **285**
B.1 ACTIV Introductory appendices . . . 285
B.2 ACTIV components . . . 292
B.2.1 User interface . . . 292
B.2.1.1 ACTIV controller instruction set . . . 292
B.2.1.2 GUI use . . . 295
B.2.2 Sensor paper . . . 296
B.2.3 Sensor paper . . . 306
B.2.4 Controller base PCB schematic . . . 320
B.2.5 GUI PCB schematic . . . 321

List of Figures

3.1 Historic average annual out-of-pocket health expenditure per capita [130], compared to median weekly wage [156, 160], and mean of 20th-centile weekly household income [156]. Out-of-pocket health expenses are exclusive of charitable and private insurance spending. 36

4.1 Example breakdown of a pre-filled pen device for the delivery of SC insulin. 42

4.2 Examples of daily profiles comparing MDI with delivery via an insulin pump [199]. 44

4.3 Portion of individuals with type-one diabetes with publicly-funded insulin pumps. Deprivation quintiles as per NZDep2006; 1 is the least deprived, and 5 is the most deprived, recreated from data from [151]. 52

4.4 Pump prevalence showing only publicly-funded insulin pumps as a function of deprivation centile. 1 is the least deprived, and 10 is the most deprived, recreated from [151] 53

4.5 Renderings of prototypes of the ULC pumps. (a) depicts the traditional, motor-driven pump, and (b) the mechanically-driving pump design. . . 72

4.6 Energy transformations within a traditional insulin pump. 73

4.7 (a) Energy transformations of the novel mechanically-driven ULC pump. Thick arrows denote energy transformations associated directly with insulin delivery, whereas thin arrows denote control. (b) Picture of the escapement mechanism of the prototype. 74

4.8 Lila Moss at Milan Fashion Week 2021 with an Omnipod™(Insulet Corporation, Massachusetts, USA) patch pump prominently on display. . . 77

4.9 The Tech-ISM framework which enables adoption of technological innovations within medicine [17]. 79

5.1 Clarke error grid [406] for the novel light-based pulse glucometer. 95

6.1 Compartment model representation of the overall system. 106

6.2 Depiction of k_{empt} as a function of q_{sto}, adapted from [439] 108

6.3 Endogenous pancreatic release as a function of the blood glucose level. . 111

6.4 Test protocol for the MMOIST 113

6.5 Example validation data from basic fitting of n_l, x_l, and S_I to data obtained from the MMOIST. 115

7.1 Ventilation delivered to two patients from a single ventilator in a parallel configuration. Inspiratory effort is delivered to both patients simultaneously. In this example both patients have equal lung characteristics. . . 128

7.2 Laboratory-simulated results of 4-way shared ventilation in a parallal manner, adjusting the compliance of different patients and attempting to rectify the variations in tidal volume through the use of differing diameter ETTs, reproduced from [528]. 131

7.3 In-series ventilation as is made possible by the ACTIV system. Breath is delivered first to one patient and then the other. 133

8.1 Fully assembled ACTIV flow and pressure sensor. 139

8.2 Example data snippet showing the sensor output against the ventilator (PB840) captured data. Note the data clipping at $75L \cdot min^{-1}$ for the sensor. The artefact after the flow returns to zero is from moving parts in the respiratory circuit. Clipping at the maximum flow can be seen in the second half of the data. 140

8.3 Bland-Altman plot demonstrating the error of the flow sensor across 80 seconds, $N = 4000$. The significant errors are due to sampling at a rate relatively low compared to the near-vertical increases in flow rate, and the smoothing which is done by the ventilator. (b) is cropped to depict only data within 2σ. 142

8.4 PANDAPeep Gen2 Inline pressure drop valve. Made with 3D-printed components and other common mechanical components. Image from: https://www.thingiverse.com/thing:4316582. 148

8.5 Approximation of the relationship between rotation **from fully closed** and pressure across the PANDAPeep Gen2 Inline valve. It is variable as a function of the exact assembly process and components used. 149

9.1 Depictions of the valve in the two operating positions. 157

9.2 Partial exploded view of the valve. For a colour key see [50]. 157

9.3 State machine implementation of the control system to determine when to switch the status of the valve. 163

10.2 Image of the complete ACTIV setup, with colour-coordinated sides for convenience. 169

10.3 Procedure for balancing ventilation between a healthy and an unhealthy patient. (a) specifies the PANDAPeep valves for use during the process, which is shown in (b). Note ↑ indicates to tighten the corresponding valve, except in the case of V_{PIP} which is to increase the driving pressure of the ventilator. 172

10.4 Breath characteristics from the two patients, as measured by the FPS at the 'patient'. A) represents a change in PEEP to align the data from the flow and pressure sensors with the mechanical ventilator. B) represents the physiological change of the left lung from 0.10 $L \cdot cmH_2O^{-1}$to 0.05 $L \cdot cmH_2O^{-1}$as per Section 10.1.1; C) is the protective introduction of an inspiratory pressure drop on the healthy lung as per Section 10.1.1;2; D) is the increase in driving pressure from the mechanical ventilator as per Section 10.1.1;3; E) is the introduction of external PEEP for the unhealthy lung; F) another small increase in driving pressure from the ventilator; and G) is another small increase in the pressure drop in the inspiratory circuit of the healthy lung. This balancing process is shown and discussed at https://www.youtube.com/watch?v=FqLRors0JA4. . 173

10.5 Example of incomplete expiration. The right lung is inflated, and slowly deflates until a breath delivered to the left lung at $t = 38.4s$, at which time expiration for the right lung pauses, until the left lung has also expired. 176

A.1 Prototype of the motor-driven pump design. 267

A.2 Prototype of the spring-driven pump design 268

B.1 State diagram and instructions for use of the interface for plotting and sending commands to the system controller. 295

B.2 Explanation of the screen layout when in plotting mode. 295

List of Tables

4.1 Requirements for a publicly-funded prescription for an insulin pump under either the severe hypoglcaemia or glycaemic control criteria, recreated from [212]. 48

4.2 Potential adoption scenarios for the ULC insulin pump. Scenario 1 represents no change in total insulin pump adoption, but assumes that only those who currently have pumps will adopt the ULC pump. Savings are represented as positive values, and costs as negative values. All values are in thousands of New Zealand Dollars. T1D — Individuals with type-one diabetes; T2D — Individuals with type-two diabetes 65

4.3 Testing results from the laboratory tests evaluating the ULC insulin pump's ability to deliver boluses compared against other devices currently available in New Zealand. 75

4.4 Testing results from the laboratory tests evaluating the ULC insulin pump's ability to deliver a constant basal rate compared against other devices currently available in New Zealand. 76

5.1 Comparison of the novel light-based pulse glucometer with other commercially available devices: The Enlite 2 (Medtronic Inc., California, USA), the FreeStyle Libre FGM (Abbott Diabetes Care Inc., California, USA), and the G6 (DexCom Inc., California, USA). 97

5.2 Potential adoption scenarios for the ULC CMG. Scenario 1 represents no change in total CGM, but assumes that only those who currently have CGMs will adopt the ULC CGM. Savings are represented as positive values, and costs as negative values. All values are in thousands of NZ dollars. T1D — Individuals with type-one diabetes; T2D — Individuals with type-two diabetes 101

6.1 Example of a parameter set used for the forward simulation of a digital twin. Sources: (1) - [439], (2) - [442], (3) - [441], (4) - [443], (5) - [444]. Note A: These are parameters which change as a function of carbohydrate intake. Note B: Measured. Note C: Solved for in steady state conditions. 112

6.2 Identified values for fitted parameters for the MMOIST. 114

6.3 Fitting errors for the MMOIST. 114

8.1 Operation ranges of the various configurations of the flow/differential pressure sensor. The combination of the 15-10 mm Venturi and the 125 Pa differential pressure sensor is the most used by the authors. Note: The operational range shown here is beyond the '100%' value specified by the manufacturer [535], but has shown to be relatively reliable. . . . 146

8.2 Resolution of the flow sensor for a variety of configurations, all values in $L \cdot min^{-1}$ unless otherwise indicated. **with the differential pressure sensor configured in linear mode**, and with a **10-bit ADC**. The inter tenth-centile resolutions are shown. 146

B.1 Specific reasons against the use of ventilators for multiple patients, and the safe mitigation of each reason. The wide range of valid criticisms from the consensus statement [9] are individually addressed in the context of a series ventilation approach. *VC* volume-controlled, *PC* pressure-controlled ventilation, *PEEP* positive end-expiratory pressure, *PIP* peak inspiratory pressure, V_t tidal volume. Recreated with permission from [11]. 285

B.2 Available instructions for the control module over serial. 292

Acronyms and abbreviations

2FA	Two-factor authentication
ACTIV	Actuated, closed-loop, time-series, inspiratory valve
ADC	Analogue to digital converter
APS	Artificial pancreas system
BG	Blood glucose
BOB	Blood opitical biosensor [CGM]
BOM	Bill of materials
CGM	Continuous glucose monitor
CPAP	Continuous positive airway pressure
COVID-19	Novel coronavirus disease
DC	Direct current
DHB	District Health Board
DIY	Do-it-yourself
DKA	Diabetic ketoacidosis
ECG	Electrocardiogram
EGP	Endogenous glucose production
FDA	Food and Drug Administration
FGM	Flash glucose monitor

FSM	Finite state machine
GDP	gross domestic product
GP	General practitioner
GUI	Graphical user interface
HEPA	High-efficiency particulate absorbing
HIV	Human immunodeficiency virus
I2C	Inter-intergrated circuit protocol
ICING2	Intensive control insulin-nutrition-glucose model system
ICU	Intensive care unit
IOT	Internet of things
ISO	The International Organization for Standardisation
LEAPS	Low-cost, equitable APS
LED	Light-emitting diode
MDI	Multiple daily injections
MMOIST	Model-based modified OGTT insulin sensitivity test
MIR	Mid infrared
NIR	Near infrared
NSIO	non-specific interoperability
NZ	New Zealand
OpenAPS	Open artificial pancreas system
OGTT	Oral glucose tolerance test
PANDA	PANDAPeep Gen2 Inline Valve — a DIY PEEP valve
PCB	Printed circuit board
PEEP	Positive, end-expiratory pressure
PIP	Peak inspiratory pressure
POC	Point of care

PPE	Personal protective equipment
PPG	Photoplethysmography
RT-CGM	Real-time continuous glucose monitor
RTC	Real-time clock
RRI	Responsible research and innovation
SD	Standard deviation
SIO	Specific interoperability
SMBG	Self-monitored blood glucose
SME	Small- and medium- sized enterprises
STAR	Stochastic targeted glycaemic control
SPI	Serial peripheral interface protocol
TAR	Time above range
TB	Tuberculosis
TBR	Time below range
TDD	Total daily dose
Tech-ISM	Framework for technology adoption
TIR	Time in range
UI	User interface
UK	United Kingdom
ULC	Ultra-low cost [insulin pump]
USA	United States of America
USD	USA dollars

Abstract

Medical device innovation provides access to healthcare. Innovations come about because of pressures, in particular financial pressures, and access to care. With increasing interoperability of devices, distinction is made between devices with specific interoperability (SIO) only able to communicate with a pre-determined range of other devices, and non-specific interoperability (NSIO). Devices with NSIO pose substantially greater potential benefits by allowing long-term system wide innovations.

Scales of innovation are discussed, where short-term innovations meet an immediate need, such as the inundation of intensive care units (ICUs) in the COVID-19 pandemic. Medium-term innovations see either incremental increase in efficiencies, or an increase in interoperability which enables subsequent innovation. Long-term innovations are disruptive, systemic changes, often enabled through the use of increasing interoperability. The uptake of innovation is often lacking, but through the use of a framework such as Tech-ISM the chance of adoption is increased. This framework sees establishment and fostering of close relationships with a range of end users, decision makers, and industry partners.

Diabetes technologies are presented as examples of innovation. Insulin pumps are an effective method of delivering insulin, and see considerable benefit in control. Widespread adoption of insulin pumps is posed through the development of an ultra-low cost (ULC) insulin pump, made possible by the separation of hardware and computation, and costing $12\times - 20\times$ less than currently-available devices, both for a traditional-style insulin pump, and also a novel spring-driven design.

Initial results show similar accuracy to current commercially-available insulin pumps, with a mean error of 0.64%, the same as the MiniMed™640G (Medtronic, Dublin, Ireland) for 1 U boluses, and mean error of 0.06% for 10 U boluses. Basal windows of 1 hour are similarly accurate, with 100% within $\pm 15\%$, 92% within $\pm 10\%$, and 84% within $\pm 5\%$, again very similar to the MiniMed™640G. The ULC insulin pump is a solution to the economic infeasibility of insulin pumps for the majority of New Zealanders.

System-wide adoption of insulin pumps would see considerable economic benefit for New Zealand, in particular with a patch pump. Several possible adoption scenarios are presented. Annually, direct savings associated with less insulin use and current public investment in insulin pumps is expected to total \$6.6M - \$25.3M, indirect savings from reduction of expensive complications are expected to save \$2.5M - \$25.5M, with direct costs of \$0.8M - \$25.7M. Projections are for a total overall system saving of \$8.3M with no additional uptake of insulin pumps, but only replacing current insulin pumps with the ULC alternative, to \$25.0M with widespread adoption. These figures do not account for additional savings made possible through future long-term development of smart, automated healthcare systems.

A continuous glucose monitor (CGM) is a device that estimates blood glucose (BG) every 1-5 minutes, replacing discrete, invasive self-monitored blood glucose (SMBG) measurements as required four to ten per day currently for approximately 40,000 - 60,000 New Zealanders with diabetes who administer insulin. Current CGM use is limited, but relatively unknown, due to no public funding, with expert estimates at 2-8% prevalence among individuals with type-one diabetes. A low-cost alternative is presented in the form of the blood optical biosensor CGM (BOB CGM) at an annual cost $10\times - 20\times$ less expensive than current devices. Initial, un-calibrated results show promise, with 91% of BG results deemed clinically accurate, and a further 8% sufficiently accurate to not cause treatment error. Fundamentally, cost savings arise from allowing access to otherwise inaccessible data, and thus turning the current data monopoly into a data market. Substantial economic benefit is seen from direct savings from current monitoring of diabetes disease progressions with SMBG and glycated haemoglobin (HbA1c), and also indirect savings from earlier identification of worsening diabetes control. Various adoption scenarios are presented, with overall annual economic savings of $1.9M - $25.1M.

Another medical innovation is presented in the form of the actuated, closed-loop, time-series inspiratory valve (ACTIV) dual ventilation system. This innovation is a short-term example, developed under pressure of inundation of the healthcare system due to the novel coronavirus disease (COVID-19). The basic operating premise is ventilatory effort from a single mechanical ventilator is delivered first to one patient, and subsequent to a valve switching state, to a second patient. The system is a solution that addresses valid concern for multiple ventilation from a consensus of oversight bodies for ICU

treatment, in particular personalised therapy and monitoring, especially in the case of changing pathology. The system is designed to be low-cost, robust, portable, and readily manufactured in low-resource environments. Thus, it has an Arduino (Arduino, Massachusetts, USA) controller, and requires a 5.0 $V\overline{\overline{\cdots}}$power supply.

The system requires a flow and pressure sensor for detection of inspiration, and subsequent valve switching. A custom-made 3D-printed Venturi interfaced with simple electronics with an analogue $0.0 - 5.0\ V$ output signal is presented. The sensor is validated against data from mechanical ventilation devices to be accurate over the range of $5 - 75L \cdot min^{-1}$, with a Pearson Correlation ≥ 0.95 for flow and pressure, typically ≥ 0.97 in 5 S bins at $f_s = 50\ Hz$. Additional components are a 3-D printed pressure drop device in the form of the PANDAPeep Gen2 Inline valve, and off-the-shelf one-way valves, airway filters, and 22 $mm\oslash$ tubing.

The switching ACTIV valve is another 3D-printed component, and uses a common HXT12K servo motor, or similar, for interoperability. The Arduino-based control system is a basic finite state machine (FSM) relying on low-pass filtered flow sensor data, implemented through a circular buffer, for state changes. These state changes, in combination with various necessary delays for safety, dictate the change of state of the ACTIV valve, and thus to which patient ventilation effort is delivered. An example of two considerably unbalance patients, with compliance $C = 0.10L \cdot cmH_2O^{-1}$and $C = 0.05L \cdot cmH_2O^{-1}$, being safely and efficiently balanced to achieve equal tidal volume is demonstrated.

Without innovations such as the diabetes technologies and ACTIV system, care will

become increasingly rationed. Rationing of diabetes devices with high effectiveness, but also high cost, is already seen in the lack of public funding for CGM devices, and funding for only 8-10% of individuals with type-one diabetes to access insulin pumps, despite significant proven benefits of both of these devices. Since 2000, increases in direct out-of-pocket expenditure have grown an average of 4.3% per annum, compared to median wage growth of 3.2%, and inflation of 2.6%. These trends show that the rationing of healthcare is being seen in a reduction of access to publicly-funded services. Given an average annual wage increase of only 1.6% for the lowest 20^{th} centile, individuals who are least well off are less able to afford the required personal expenditure to attain the same access the healthcare. Therefore, access to healthcare is seeing worsening equity of access.

With increasing demand for healthcare, and a taxation base stagnant at best, relying only on intrinsic changes, New Zealand faces significant taxation increases, or drastic reductions in healthcare services. The alternative is to increase the efficiency of healthcare delivery methods, using extrinsic, disruptive changes. These changes are only made possible through innovation informed by strong clinical insight, developing mechatronic devices with broad, non-specific interoperability, if not open-source design. This approach provides equitable access to care, and provides the necessary framework for automation of healthcare services, including diagnostics, prognostics, and personalised care models under a one-method-fits all approach. This widespread technological innovation and adoption poses significant increase of access to care, combating current inequities.